

Robot-based psychological intervention program for the prevention of sexual abuse in children

Submission date 19/06/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/07/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/09/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

Child sexual abuse is a serious issue with serious consequences. Self-care education programs can improve children's awareness, knowledge, and skills to defend themselves against sexual abuse. The aim of this study is to evaluate a psychological intervention program with a smart robot for sexual care in elementary school children.

Who can participate?

Children aged 8-12 (elementary school) in Ghaenat City, Iran in 2019

What does the study involve?

Children are randomly allocated to the test and control groups. First, all students fill in a questionnaire. The participants in the test group attend 10 45-minute sessions of psychological intervention (with robots) in 5 weeks (two sessions per week). At the beginning of each session, the researcher explains the session's topic and then a robot teaches the content of the session via tools such as PowerPoints and movies. The material related to each session is emphasized after the training, and finally, the educational content of each session is reviewed and the possible questions and tasks of the previous session are answered. In the end, assignments are allocated to the participants to practice the skills learned during the session. On the other hand, no intervention is carried out for the participants in the control group. After the education process, both groups fill the questionnaire again. Three months after the intervention, all of the participants fill the questionnaire one more time as the follow-up stage. Educational sessions are held for the control group at the end of the study.

What are the possible benefits and risks of participating?

The benefits of this intervention are prevention and awareness of child sexual abuse. There is no risk to the participants.

Where is the study run from?

Private center, Khorasan, Ghaenat (Iran)

When is the study starting and how long is it expected to run for?
February 2019 to December 2019

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Mohammad Tahan
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of a robot-based psychological intervention program on sexual care in elementary-school children

Study objectives
Does a robot psychological interventional program affect the sexual care of elementary school children?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 28/07/2019, Iran National Committee for Ethics in Biomedical Research (Islamic Azad University, Bojnourd Branch - Research Ethics Committee, Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran; +98 (0)21 81455618; ethics@behdasht.gov.ir), ref: IR.IAU.BOJNOURD.REC.1398.004

Study design

Quasi-experimental research with a pretest-posttest design and a control group

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Sexual care of elementary school children

Interventions

After receiving a license from the vice-chancellor for research and technology of Islamic Azad University, Birjand Branch, ethical code in research, and permission from the head of education in Qaen and communicating with elementary schools of the city, parents suggested by teachers are invited to participate in a briefing meeting to explain research objectives and implementation stages. Written informed consent is obtained from all parents and they are ensured of the confidentiality terms regarding their personal information. In a meeting, 80 children are selected and allocated to two test and control groups. First, all students fill the questionnaire and the scores obtained are considered as a pretest. The participants in the test group attend 10 45-minute sessions of psychological intervention (with robots) in 5 weeks (two sessions per week). The first session is held in Payam Salamat Clinic. At the beginning of each session, the researcher explains the session's topic and then a robot teaches the content of the session via tools such as PowerPoints and movies. The material related to each session is emphasized after the training, and finally, the educational content of each session is reviewed and the possible questions and tasks of the previous session are answered. In the end, assignments are allocated to the participants to practice the skills learned during the session. On the other hand, no intervention is carried out for the participants in the control group. After the education process, both groups fill the questionnaire again and the scores are considered as a posttest. Three months after the intervention, all of the participants fill the questionnaire one more time as the follow-up stage. In order to adhere to research principles, educational sessions are held for the control group at the end of the study. A summary of the content of each session is presented in:

1. Training program -Introduction to robots
2. Introducing, familiarizing and informing about body parts
3. Identifying, informing and becoming acquainted with important and private body parts
4. Learning to recognize people (distinguishing family members, acquaintances and strangers)
5. Learning how to connect with family members, acquaintances and strangers
6. Identifying dangerous and harmful situations and moments
7. Identifying and introducing dangerous and harmful situations and moments and how to deal

with them (family)

8. Identifying and introducing dangerous and harmful situations and moments and how to deal with them (acquaintances)

9. Identifying and introducing dangerous and harmful situations and moments and how to deal with them (strangers)

10. Overviewing past topics and reviewing all items considered

Intervention Type

Behavioural

Primary outcome(s)

Children's knowledge and awareness of sexual abuse measured using Questionnaire of Children's Knowledge and Awareness of Sexual Abuse at 6 months

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

20/12/2019

Eligibility

Key inclusion criteria

1. Willingness to participate in the study

2. Aged 8-12 years

3. No history of acute psychological and physical diseases (based on interviewing and health checklist of students)

4. Consent form completed by parents

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

12 years

Sex

All

Total final enrolment

80

Key exclusion criteria

1. Absence from one educational session
2. Taking specific drugs
3. Simultaneous participation in a similar educational intervention
4. Unwillingness to participate in the research

Date of first enrolment

01/08/2019

Date of final enrolment

20/12/2019

Locations**Countries of recruitment**

Iran

Study participating centre**Private center**

Khorasan

Ghaenat

Iran

97616

Sponsor information**Organisation**

Islamic Azad University of Birjand

ROR

<https://ror.org/02p42am41>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/02/2021	09/03/2022	Yes	No
Protocol article		01/03/2023	15/09/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes